993,309

PATENT SPECIFICATION

DRAWINGS ATTACHED

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COMPLETE SPECIFICATION

Improved Hypodermic Injector

We, EXPRESS INJECTOR COMPANY LIMITED, a British Company of 143 New Bond Street, London, W.1, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement: —

The invention relates to an improved hypodermic injector of the kind capable of discharging a jet of liquid through the skin of a patient without the use of a hypodermic needle. Such injectors are adapted to be fitted with an ampoule or container for liquid medicament and it has been proposed heretofore to expel the medicament from a discharge orifice in one end of the ampoule, by introverting the ampoule, whilst at the same time supporting it against bursting or collapse by means of a surrounding layer of soft rubber.

It has also been proposed to discharge medicament from an ampoule in two pressure stages and to this end the ampoule has been fitted with a piston formed of flexible material the arrangement being such that the first high pressure stage is produced by operation of a plunger which deforms the centre of the piston, whilst the second and lower pressure stage is produced by the operation of a secondary plunger which displaces the piston in the ampoule.

In both the above techniques a degree of the energy used for the displacement of the liquid medicament from the ampoule, is absorbed by rubber or like flexible material associated with the ampoule. Moreover, due to the difficulty of producing rubber-like components to exactly specified requirements, variations may occur in such components, which result in different injection depths and pressures between injections. If there is any appreciable fall of pressure during the first stage of injection, liquid may be dispersed at high pressure just beneath the skin and this may prove very painful. It has been found essential therefore, when other than very small quantities of liquid are to be injected, to maintain pressure during the very short period in which the skin penetrating stream of liquid leaves the injector, in order that the piercing of the skin is incisive and instant.

It is one object of the invention therefore to provide an injector capable of making an incisive penetration to the depth required.

In our co-pending applications nos. 10352/60 (Serial No. 964584) we have described an ampoule for liquid medicament which is capable of being introverted to cause said medicament to be discharged and a further object of the invention is to provide an improved needleless hypodermic injector for use with such an ampoule.

According to the invention a hypodermic injector comprises a housing for an ampoule in the form of a thin walled shell of uniform wall thickness capable of being introverted, means in said housing for supporting the ampoule against any expansion when the content thereof is subjected to pressure, and means for imparting to a closed end of said shell, first a percussive force to produce a transient high pressure discharge of medicament in the ampoule, and subsequently a compressive force capable of introverting the said shell and discharging the remainder of the medicament in the ampoule at reduced pressure.

Further according to the invention a hypodermic injector comprises a housing for an ampoule in the form of a thin walled shell of uniform wall thickness capable of being introverted, means in said housing for sup-

porting the ampoule against any expansion when the content thereof is subjected to pressure, a nozzle cap having a discharge orifice therein, arranged to make sealing contact with a discharge nozzle on said ampoule, and means for imparting to a closed end of said shell, first a percussive force to produce a transient high pressure discharge of medicament in said ampoule, and subsequently a compressive force capable of introverting the said shell and discharging the remainder of the medicament in the ampoule at reduced pressure.

In the above constructions the aforesaid housing is arranged to support the walls of an ampoule in such a manner that substantially no distension of the ampoule shell is permitted either on application of said first percussive force or said subsequent compressive force.

In order that the invention may be more readily understood reference will be made to the drawings accompanying the provisional specification and to the accompanying drawings which illustrate by way of example preferred embodiments thereof.

In the drawings accompanying the Provisional specification:—

Fig. 1 is a sectional elevation of a hypodermic injector showing one form of ampoule fitted therein.

Fig. 2 is a part sectional elevation of the injector of Fig. 1 showing the parts in the position which they adopt after the ampoule has been fully introverted.

In the drawings accompanying the Complete specification:—

Fig. 3 is a sectional elevation of an alternative form of hypodermic injector showing another form of ampoule fitted therein and having the discharge orifice arranged in a part of the injector.

Fig. 4 is a sectional view on an enlarged scale of the ampoule shown in Fig. 3.

Fig. 5 is a sectional fragmentary view of the injector housing modified to support an alternative form of ampoule.

Fig. 6 is a sectional view on an enlarged scale showing yet another form of ampoule and Figs. 7 and 8 are further sectional views on an enlarged scale and showing members incorporating the discharge nozzles of the ampoules partly driven into the ampoule shells.

Referring to Figs. 1 and 2 of the drawings the injector comprises a tubular metal housing 10 having a socket in one end for receiving a cylindrical ampoule 11. The ampoule which is described more fully in our said co-pending application No. 10352/60 (Serial No. 964584), comprises an elongated shell of thin ductile material, closed by a plug 12 having a minute discharge orifice 13. The ampoule is closely and rigidly supported in the housing 10 and is retained therein by a cap 14 which engages a flange 12*a* on the plug 12 and screws onto the housing.

Slidably mounted in the housing 10 is a plunger 15 which is provided with a head 15*a* of slightly smaller diameter than the bore of the ampoule, which head is radiused as shown and normally rests on the closed end of the ampoule 11.

The upper end of the housing 10 is provided with a screw thread and has secured thereto a barrel 16 enclosing a spring operated mechanism for striking and driving the plunger 15. The said spring operated mechanism comprises a tubular guide member 17 slidable in the barrel 16 and a further tubular guide member 18 also slidable in said barrel, the two guide members 17 and 18 being arranged in telescopic relationship. Between the flanged ends of the two guide members are two springs 21 and 22 capable of being compressed into the condition shown in Fig. 1 for forcing the two guide members 17 and 18 rapidly apart.

The said guide members 17 and 18 are retained locked together against the loading of the springs 21 and 22 by means of a ball and cone locking mechanism. This mechanism comprises a spindle 23 slidable in the guide member 17 and normally loaded upwardly therein into the position shown in Fig. 1 by means of a spring 24, the upward movement of the spindle being limited by a cap 20. The lower end of the guide member 17 is provided with a number of radial slots 25 in which are located a corresponding number of balls 26. The guide member 18 is formed with a small circumferential recess 18*a* in which the balls 26 seat when the injector is in the condition shown in Fig. 1, the balls being retained in said recess by means of a cone-shaped extension 23*a* on the lower end of the spindle 23. In the position of the parts shown in Fig. 1, it will be seen that the guide members 17 and 18 are free to slide in the barrel 16, but are loaded upwardly therein by means of a light spring 27, so that if the locking mechanism is released, the springs 21 and 22 react against the guide member 17 which then abuts against an inwardly directed flange on the cap 29 on the upper end of the barrel 16.

The release of the springs 21 and 22 is effected by means of a button 28 on the upper end of the spindle 23. With the parts in the position shown in Fig. 1 depression of said button causes the spindle 23 to be displaced until the thin end of said cone-shaped extension 23*a* is aligned with the balls 26. In this position of the spindle 23 the balls 26 are permitted to move radially inwards and leave the recess 18*a* in the guide member 18, which thereupon snaps downwardly and strikes the plunger 15.

The effect of the guide member 18 strik-

ing the plunger 15 produces a percussive force on the ampoule 11, the closed end of which is suddenly deformed under said force causing a small amount of the medicament in the ampoule to be discharged under a high pressure. The free run of the guide member 18 before striking the plunger 15 and therefore the force with which it strikes said plunger is adjustably controlled by screwing the cap 29 up or down on the barrel 16.

The kinetic energy of the released guide member 18 is largely utilised to produce the sudden deformation of the closed end of the amopule, but after said guide member has been brought nearly to rest, what remains of such energy is employed together with the loading remaining in the springs 21 and 22 to drive the plunger 15 into the ampoule. This subsequent compressive force on the ampoule causes it to be introverted comparatively slowly, into the condition shown in Fig. 2, in which all the medicament has been discharged.

The discharge of the medicament from the ampoule in two pressure stages enables first the medicament to penetrate to the required depth for the particular injection and secondly the medicament to be dispersed into the tissues at this depth, at a sufficiently reduced pressure to prevent said tissues being damaged. The use of two springs to drive the plunger 15 into the ampoule during the introversion of the ampoule, has the advantage that the resonance of one spring is counter-balanced by the resonant frequency of the other, thus inequalities of pressure which cause pain during an injection are substantially prevented.

In order that the springs 21 and 22 shall not be inadvertently released the spindle 23 is provided with a safety device in the form of a small sliding latch 31. This latch is a slidable fit in a recess in the upper part of the guide member 17 and is retained therein by a dished-shaped washer 33 and a spring not shown, arranged to react between the skirt of said washer and one end of the latch. The spindle 23 passes through a hole in the centre of the latch and is provided in the region of said hole with a reduced neck 23*b*, the arrangement being such that when the latch is slid one way the spindle 23 is free to move, but when the latch is slid the other way the edge of the hole therein engages in the neck 23*b* of the spindle and the spindle is locked.

The latch 31 may be moved by the rotation of a control ring 34 having a cam surface on its inner face, which is arranged to engage one end of the latch and displace it against its spring loading. The mechanism of the latch and control ring is more fully described in my co-pending application No. 10353/60 (Serial No. 964585).

Prior to using the injector the springs 21 and 22 are compressed by means of a loading device having a hollow plunger which is arranged to engage a step 20*a* on the spindle retaining cap 20. This device simply comprises a supporting socket for receiving the housing 10 and for providing a seat for the shoulder 10*a* thereon, and a lever mechanism for moving said hollow plunger towards said socket.

In order that the assembly comprising the guide member 17, the spindle 23 can be moved downwardly in the barrel 16 during the loading of the springs, the inwardly directed flange at the upper end of the cap 29 is provided with a number of radial recesses 29*a*. For the same reasons the lower edge of the ring 34 is provided with a number of outwardly directed projections 34*a* which are capable of passing through said recesses 29*a* when the ring 34 is rotated into the locking position of the safety latch. In the unlocked position of the safety latch, the ring 34 is rotated into a position in which on depression of the button 35, the projections 34*a* abut the top of the cap 29, so that only the spindle 23 is moved downwardly.

After the spring mechanism has been compressed by the loading device, the spring 27 moves the assembly of springs and guide members upwardly to the top of the barrel 16. At the same time the spring 35 moves the plunger 15 to its retracted position shown in Fig. 1.

In an alternative embodiment not illustrated the plunger 15 is normally maintained under spring loading, in engagement with the lower end of the guide member 18 and the enlarged head 15*a* of the plunger is spaced from the closed end of the ampoule 11. In this arrangement when the guide member 18 is released from the guide member 17, the plunger 15 has a free run before striking the head of the ampoule and the percussive force on the plunger 15 is substantially the same as that when the plunger is struck by the guide member 18 as in the arrangement of Fig. 1.

In the alternative arrangement illustrated in Fig. 3 the injector is intended to receive an ampoule having a nozzle of comparatively large bore. In this embodiment the discharge orifice 44 for the medicament is located in a nozzle cap 41 adapted to be screwed on to the housing 40, thus the rather expensive operation of making a minute discharge orifice in the closure plug of each ampoule is avoided.

As will be more clearly seen in Fig. 4 the closed end of the ampoule shell 42 is provided with a shallow step 42*a* and the housing 40 of the injector is provided with a shoulder 40*a* shaped to fit closely into said step. The shell 42 of the ampoule has fitted into its open end a plug 43 of synthetic resinous material, the plug having a

thin walled nozzle 43*a* with a comparatively large bore, which fits closely into a tubular extension 41*a* on the outer end of the nozzle cap 41. The plug 43 is sealed to the shell 42 by means of a ring 45 which makes an interference fit with said shell. The nozzle cap is also fitted with a rubber or like ring 46 which serves as a non-slip cushion when the injector is applied to the skin.

The operation of the plunger 15 and plunger head 15*a* is the same as that described with reference to Figs. 1 and 2. Thus when the radiused plunger head 15*a* is driven against the closed end of the shell 42 under the percussive force of the tubular guide member 18, a transient discharge of medicament under high pressure is ejected through the discharge orifice 44. Any increase in pressure within the ampoule causes the thin wall of the nozzle 43*a* to be pressed into sealing contact with the inner wall of the tubular extension 41*a*.

Figs. 5 and 6 show slightly modified forms of ampoule shell. Thus the shell 42 in Fig. 5 is formed with a bevel 42*b* at its closed end and the surrounding housing 40*b* is provided with an inclined seat 47 to give rigid support to the reduced end of the shell when it is struck by the plunger head 15*a*. The shell 42 shown in Fig. 6 is flat at its closed end and the striking of the plunger head 15*a* thereon simply deforms the closed end to provide the high pressure stage of the discharge from the ampoule.

The ampoules after charging with medicament, are closed by a cap such as the cap 48 shown in Fig. 4. This enables the ampoules to be stored with the contents in a sterile condition, but it may not prevent one or more air bubbles being present in the contents. Before an injection is made, it is important that any air in the ampoule should be expelled and to this end provision is made for priming the injector when the ampoule is fitted.

Fig. 7 shows an arrangement in which the plug 43 is not fully driven home into the shell 42 a slight clearance of the order of 0.015 inches, being left at 49 when the ampoule is filled.

Fig. 8 shows a similar arrangement to Fig. 7 except that the ring 45 is provided with a downwardly directed skirt 45*a* to provide a more effective seal between the shell 42 and the plug 43.

When it is desired to make an injection the springs 21 and 22 are compressed in the manner described with reference to Figs. 1 and 2, and the nozzle cap 41 is removed from the injector. The cap 48 is removed from the ampoule which is then inserted in the housing 40 whilst the plug 43 is spaced from the shell 42 by the clearance at 49. The nozzle cap 41 is then screwed on and during its final tightening the plug 43 of the ampoule is forced fully home into the shell 42 causing a small amount of medicament together with any air bubbles in the ampoule, to be forced out of the orifice 44. The injector is then ready to make an injection.

In all the above arrangements the walls of the ampoule are rigidly supported by the metal housing of the injector at all times during the injection and the minimum amount of the energy produced by the impact of the plunger on the ampoule is lost. This results in an accurately discharged jet of medicament with little or no variation of adjustment to the injector for a very wide range of skin subjects.

There being no moving piston in the ampoule, there is no danger of damage to the mechanism of the injector due to medicament leaking at high pressure from a moving seal in the ampoule.

WHAT WE CLAIM IS:—

1. A hypodermic injector comprising a housing for an ampoule in the form of a thin walled shell of uniform wall thickness capable of being introverted, means in said housing for supporting the ampoule aginst any expansion when the content thereof is subjected to pressure, and means for imparting to a closed end of said shell, first a percussive force to produce a transient high pressure discharge of medicament from the ampoule, and subsequently a compressive force capable of introverting the said shell and discharging the remainder of the medicament in the ampoule at reduced pressure.

2. A hypodermic injector comprising a housing for an ampoule in the form of a thin walled shell of uniform wall thickness capable of being introverted, means in said housing for supporting the ampoule aginst any expansion when the content thereof is subjected to pressure, a nozzle cap having a discharge orifice therein, arranged to make sealing contact with a discharge nozzle on said ampoule, and means for imparting to a closed end of the said shell, first a percussive force to produce a transient high pressure discharge of medicament from said ampoule, and subsequently a compressive force capable of introverting the said shell and discharging the remainder of the medicament in the ampoule at reduced pressure.

3. A hypodermic injector according to claim 1 or 2 wherein the means for imparting said percussive and compressive forces to the closed end of said shell comprises a plunger slidably mounted in said housing to engage the closed end of an ampoule rigidly supported therein, and means for driving said plunger into said ampoule to cause first a sudden deformation of the closed end of said shell and subsequently an introversion of the remainder of the shell.

4. A hypodermic injector according to

claim 3 wherein the means for driving said plunger comprise a spring operated mechanism mounted in a barrel concentric with said plunger and fixed to said housing.

5. A hypodermic injector according to claim 4 wherein said spring operated mechanism comprises a guide member slidably mounted in said barrel, a coil spring arranged to be compressed within said barrel in order to react on said guide member, means for retaining said guide member under spring loading and in spaced relation to said plunger, and means for releasing said guide member to cause it to strike and displace said plunger.

6. A hypodermic injector according to claim 4 wherein said spring operated mechanism comprises a guide member slidably mounted in said barrel, a coil spring arranged to be compressed within said barrel in order to react on said guide member, means for retaining said guide member under spring loading, means for retaining said plunger spaced from said ampoule shell and in engagement with said guide member, and means for releasing said guide member to cause said plunger first to strike and then introvert said shell.

7. A hypodermic injector according to claim 5 or 6 wherein said spring is located in said barrel between a flange on one end of said guide member and a flange on the end of a second guide member slidably mounted in said barrel, said first and second guide members having opposed tubular parts slidable one within the other to compress said spring.

8. A hypodermic injector according to claim 7 wherein said tubular parts can be locked together by a ball housed in a radial slot in the inner tubular part and capable of projecting into a recess in the outer tubular part, said ball being maintained in locking relationship with both said parts by means of a control spindle arranged to slide within the inner of said tubular parts.

9. A hypodermic injector according to claim 8 wherein said control spindle can be prevented from sliding in said tubular parts by a latch slidable transversely in said second guide member, said latch being arranged to co-operate with a neck in said spindle so as to lock it in said second guide member.

10. A hypodermic injector according to claim 9 wherein said latch is spring loaded towards its locking position and is displaceable into its unlocked position by means of a ring rotatably mounted on said second guide member, said ring having a cam surface arranged to co-operate with one end of said latch to slide it transversely in said second guide member.

11. A hypodermic injector according to claim 10 wherein said ring is provided with means serving to lock said second guide member against axial displacement in said barrel.

12. A hypodermic injector according to any one of claims 8 to 11 wherein said control spindle is spring loaded to move outwardly of said inner tubular part and is provided with a substantially cone-shaped extension arranged under said spring loading of the spindle, to urge said ball into the recess in said outer tubular part, to lock said guide members together.

13. A hypodermic injector according to claim 12 wherein said control spindle carries at its outer end a button, the arrangement being such that pressure on said button moves said spindle inwardly against said spring loading and allows said slidable guide member to be rapidly displaced under the loading of its coil spring.

14. A hypodermic injector according to any one of claims 6 to 13 wherein two coiled compression springs are located in said barrel between said slidable guide member and said second guide member, the characteristics of the springs being such that on release thereof the resonance of one spring is counterbalanced by the resonant frequency of the other.

15. A hypodermic injector according to any one of claims 7 to 14 wherein after release of said coil spring, said second guide member is capable of being displaced axially in said barrel to recompress said spring.

16. A hypodermic injector according to claim 15 wherein means are provided operative after compression of said spring to reposition both guide members in said housing.

17. A hypodermic injector according to any one of claims 3 to 16 wherein the ampoule engaging end of said plunger is slightly radiused.

18. A hypodermic injector according to claim 17 wherein said housing is arranged to receive an ampoule shell having a plain, or stepped closed end, and is provided with a seating shaped to support said shell at the perimeter of its closed end.

19. A hypodermic injector according to claim 2 or any one of claims 3 to 17 when dependent on claim 2 wherein said nozzle cap is fitted with a ring of resilient material to prevent slip on application of the injector to the skin.

20. A hypodermic injector according to claim 2 or any one of claims 3 to 19 when dependent on claim 2, wherein said housing is arranged to receive an ampoule the shell of which has been charged with medicament and closed by a plug having a discharge nozzle thereon, partially inserted into the open end of said shell, said housing being formed with an external thread on to which said nozzle cap can be screwed, first to insert said plug fully into said shell and then to retain said ampoule in said housing.

21. A hypodermic injector substantially as hereinbefore described with reference to Figs. 1 and 2 of the drawings accompanying the provisional specification.

22. A hypodermic injector substantially as hereinbefore described with reference to Fig. 3 of the accompanying drawings.

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1 SHEET

PROVISIONAL SPECIFICATION

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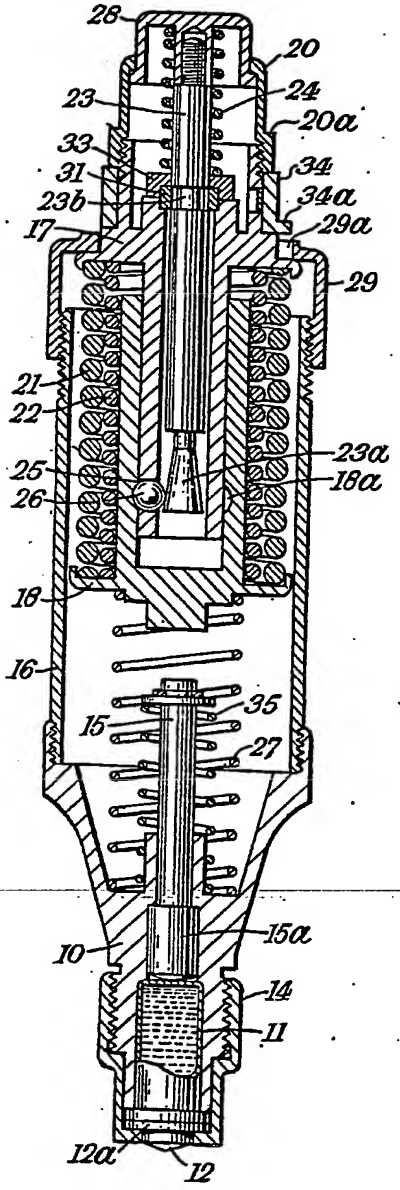

Fig. 1.

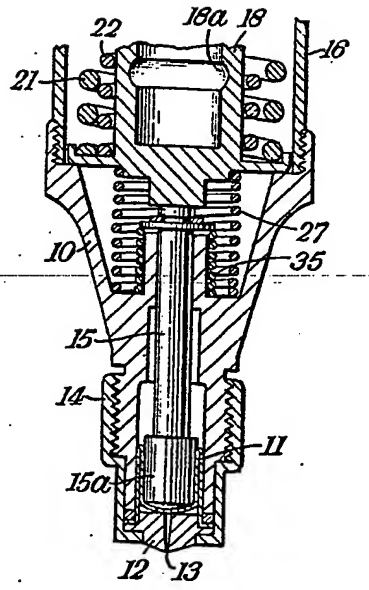

Fig. 2.

993309 COMPLETE SPECIFICATION
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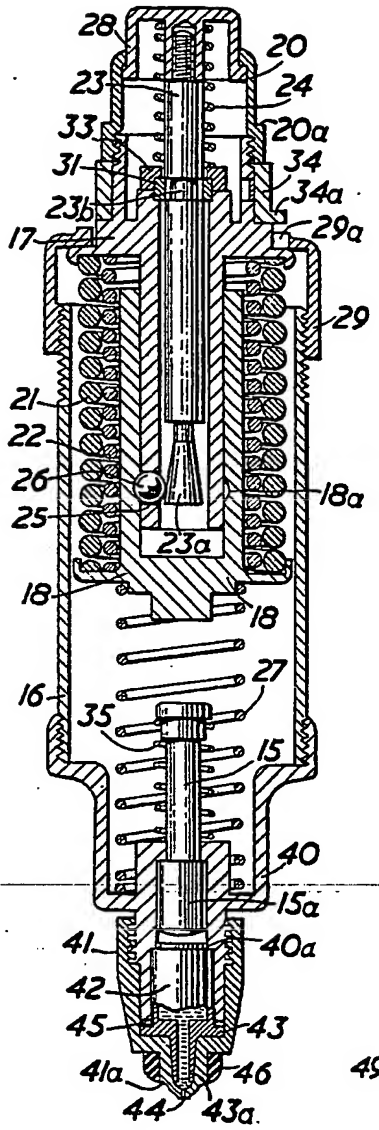

FIG. 3.

FIG. 4.

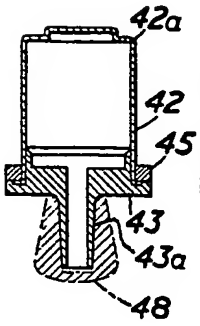

FIG. 6.

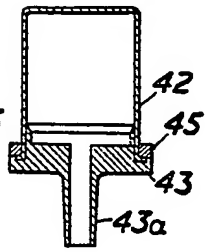

FIG. 5.

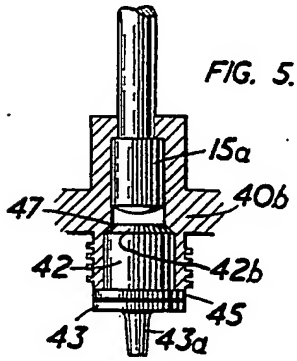

FIG. 7.

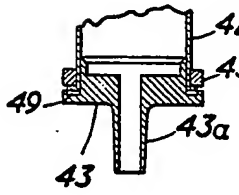

FIG. 8.